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| 09/849,044      | 05/04/2001  | Dusan Pavcnik        | PA-5252-RFB         | 9073             |

7590 10/05/2006

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| EXAMINER |
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STEWART, ALVIN J

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/849,044

Applicant(s)

PAVCNIK ET AL.

Examiner

Alvin J. Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

*Response to Arguments*

The Examiner has repeated the previous rejection in order to clarify that claims 12-18 are also rejected over the Gregory reference.

Applicant's arguments filed April 03, 2006 have been fully considered but they are not persuasive.

The Applicant's representative disagree with the Examiner's point of view disclosing that the examiner has not shown sufficient evidence to establish a prima facie case of obviousness and that the Examiner misinterpreted the Gregory reference because the Gregory reference does not teach the use of a SIS sleeve. Instead the Gregory reference teaches the use of an elastin-based sleeve and never mentions small intestinal submucosa.

After a careful examination of the Applicant's remarks, the Examiner disagrees with the Applicant's point of view. The Examiner believes that the burden of establishing a prima facie case of obviousness has been proved. The Examiner believes that the motivation to combine the references, the reasonable expectation of success and all the structure limitations meet the prima facie case of obviousness.

Regarding the Gregory reference, the Examiner wants to clarify the independent claims don't disclose the use of SIS.

Regarding claims 8, 9, 17 and 18, see col. 5, lines 36-48.

The declaration under 37 CFR 1.132 filed April 03, 2006 is insufficient to overcome the rejection of claims 1 and 3-9 based upon Douglas in view of Gregory as set forth in the last Office action because: the Applicant's representative has not discloses factual evidence and has only discloses an opinion. While an opinion as to a legal conclusion is not entitled to any weight

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the underlying basis for the opinion may be persuasive. In re Chilowsky, 306 F.2d 908,134 USPQ 515 (CCPA 1962).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas US Patent 6,090,128 in view of Gregory US Patent 5,990,379

Douglas discloses an implant comprising a plurality of stents (42) covered by a sleeve (32, 34 & 36). The stents have proximal and a distal ends. The sleeve has a length about equal to twice the length of the stent (the Examiner is referring to the two stent 42 shown in Figure 2, that are folded with the sleeve 32). The sleeve has a first portion within the inside surface of the stent and a second portion that is folded back over the proximal end of the stent (see element structure 38 in Fig. 2). The second portion extends from the proximal end to the distal end, along an outside surface of the stent (see Fig. 2). Also, the first portion and the second portion are secured to at least the distal end of the stent (see Fig. 2, elements 40, 57, 59 61). Finally, Douglas discloses stents having a frame comprising eyelets at the proximal and distal ends wherein the stents are connected to each other by biocompatible filaments.

However, Douglas does not disclose a sleeve made of SIS.

Gregory teaches an implant comprising a stent (20) and a graft (16) made of extracellular matrix. The stent has a proximal end and a distal end. The sleeve has a length about equal to twice the length of the stent (see Figs. 8-10). The sleeve has a first portion within the inside surface of the stent and a second portion that is folded back over the proximal and distal end of the stent. The second portion extends from the proximal end to the distal end, along an outside surface of the stent (see Figs. 8-10 and col. 14, lines 31-36) for the purpose of inhibiting the migration of smooth muscle cells in the treated area (see col. 1, lines 22-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the Douglas reference with the SIS sleeve of the Gregory reference in order to inhibit the migration of smooth muscle cells in the treated area.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3738

September 18, 2006.